

**REMARKS/ARGUMENTS**

In response to the Office Action mailed August 18, 2008, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, claim 1 is amended, claims 2-5 have been cancelled without prejudice and no claims have been added, so that claims 1 and 6-11 are currently pending. No new matter has been entered.

Claims 1-3 and 6-8 were rejected as being unpatentable over US 2005/0033417 to Borges et al. (Borges) in view of US 2003/0065382 to Fischell et al. (Fischell). This rejection is respectfully traversed.

Borges discloses various coatings for controlling the release rate of one or more therapeutic agents.

Fischell discloses a stent having one or more therapeutic agents and various coatings.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must to some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the

prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d, 488, 20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All the words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

None of the references, whether taken alone or in combination, disclose or suggest the subject matter claimed in amended independent Claim 1.

Specifically, neither of the references discloses topotecan in the concentration range claimed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 4 was rejected as being unpatentable over Borges in view of Fischell and further in view of U.S. Patent No. 6,485,514 to Wrenn (Wrenn). Claim 4 has been cancelled without prejudice and thus the rejection is now moot.

Claims 4 and 5 were rejected as being unpatentable over Borges in view of Fischell and further in view of U.S. Patent Application No. 2002/0004679 to Eury et al.

(Eury). Claims 4 and 5 have been cancelled without prejudice and thus the rejection is now moot.

Claims 1-3, 6, 7, and 9 and 11 were rejected as being unpatentable over U.S. Patent Application No. 2002/0123801 to Pacetti et al. (Pacetti) in view of Fischell. This rejection is respectfully traversed.

Pacetti discloses diffusion barriers for implantable medical devices. However, neither reference, whether taken alone or in combination, discloses or suggests the combination of rapamycin and topotecan in the ranges claimed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 4 was rejected as being unpatentable over Pacetti in view of Fischell and Wrenn. Claims 4 and 5 were rejected as being unpatentable over Pacetti in view of Fischell and Eury. Claims 4 and 5 have been cancelled without prejudice; accordingly, the rejections are now moot.

Claims 1-3 and 6-11 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting and being unpatentable over claim 3 of co-pending application no. 10/883,328 in view of Fischell. Accordingly, attached is a Terminal Disclaimer.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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